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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,073	04/16/2001	Asim Dasgupta	220002054822	5718

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/836,073

**Applicant(s)**

DASGUPTA ET AL.

**Examiner**

Sean R. McGarry

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12 and 20-24 is/are pending in the application.  
4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-7, 9, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The formula of claim 1 recites "A" at the position formerly "A<sup>5</sup>". In the context of the invention and the original formula it is unclear what is now claimed. Position A<sup>5</sup> of the formula as presented in the original claim 1 was defined as representing any amino acid. It is unclear whether this position is undefined now as indicated by only "A" where "A" is undefined" or whether A represents alanine. This is unclear since "A" was used as a generic amino acid defined in the body of the claim as originally filed.

SEQ ID NOS 17-19 do not fit within the formula of claim 1. SEQ ID NO: 17 ends with "I" (position A<sup>18</sup>), SEQ ID NO: 17 ends (position A<sup>18</sup>) with "A", and SEQ ID NO: 19 has "V" at position A<sup>11</sup>. The formula of amended claim 1 requires an "F" at the terminal position and which now requires an "I" at position A<sup>11</sup>, for example.

Claims 1-7, 9, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to require that A<sup>4</sup>, A<sup>12</sup>, and A<sup>17</sup> be independently E, D or Q. The claim formerly required A<sup>4</sup>, A<sup>12</sup> and A<sup>17</sup> to be independently acidic amino acids. It is not readily apparent from the original claims or the specification as filed that there is support for the subgenus now recited.

Claim 1 has been amended to recite "A" at former position A<sup>5</sup>, "I" at former position "A<sup>7</sup>", "C" at former position "A<sup>8</sup>", "I" at former position "A<sup>11</sup>", and "G" at former position "A<sup>16</sup>". The original claims defined these positions as representing any amino acid. It is not readily apparent from the original claims or the specification as filed that there is support for the species now recited at these positions.

Claim 1 has been amended to recite "Q" at former position "A<sup>10</sup>". This position was formerly defined as representing a basic or polar neutral amino acid. It is not readily apparent from the original claims or the specification as filed that there is support for the species now recited.

Claim 1 has been amended to recite specific amino acids at former positions "A<sup>13, 15 and 18</sup>". The positions were formerly defined as being independently aromatic amino acids. It is not readily apparent from the original claims or the specification as filed that there is support for the species now recited.

Claim 7 has been amended to recite only A<sup>14</sup> being phenylalanine or tyrosine. No support could be found for this limitation outside the context of also including A<sup>13, 15 and 18</sup>. It is not readily apparent from the original claims or the specification as filed that there is support for the subgenus now recited.

Claim 9 has been amended similarly as claim 7 and suffers the same issues.

All the above taken individually constitute new matter for each position as well as creating new matter for the formula itself. The formula of Claim 1 now represents a subgenus not identified in the specification of claims in the specification as filed. The specification does not clearly point one to the specific subgenus now recited. It is not readily apparent from the original claims or the specification as filed that there is support for the subgenus now recited.

Claim 1 has been amended to recite a negative proviso that the formula of claim 1 does not include SEQ ID NO: 13 when all amino acids are in the L-form. No support for this specific limitation could be found in the specification as filed. It is not readily apparent from the original claims or the specification as filed that there is support for the limitation now recited.

Claim 1 also recites that specified peptides are in isolated form when in the L-form. Again, no support for the specific limitation could be located in the specification as filed. It is not readily apparent from the original claims or the specification as filed that there is support for the limitation now recited.

Claims 1-7 and 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides of formula (1) that comprise E at A<sup>4</sup>, A at A<sup>6</sup>, I at A<sup>7</sup>, C at A<sup>8</sup>, Q at A<sup>10</sup>, I at A<sup>11</sup>, E at A<sup>12</sup>, Y at A<sup>13</sup>, F at A<sup>15</sup>, G at A<sup>16</sup>, D at A<sup>17</sup>, F at A<sup>18</sup> does not reasonably provide enablement for the full scope of formula (1). The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is maintained for the same reasons of record.

The instant invention is drawn to the use of peptides based on LAP, which inhibits viral replication. The instant claim are broadly drawn to peptides embraced within formula (1) and also includes specific peptides in claims 11 and 10, for example. Applicant has shown in Table 1, that peptides based on LAP that comprises E at A<sup>4</sup>, A at A<sup>6</sup>, I at A<sup>7</sup>, C at A<sup>8</sup>, Q at A<sup>10</sup>, I at A<sup>11</sup>, E at A<sup>12</sup>, Y at A<sup>13</sup>, F at A<sup>15</sup>, G at A<sup>16</sup>, D at A<sup>17</sup>, F at A<sup>18</sup> function to inhibit viral replication. Table 1 show that those that do not comprise these specific amino acid residues at these position do not work as viral inhibitors. Table I shows that the specifically claimed SEQ ID NO: 3 (701) did not have viral inhibitory properties. It does not appear based on applicants disclosure that one in the art would expect that peptide that are embraced within the broad formula (1) would be expected to have antiviral properties since it has been shown that only those with E at A<sup>4</sup>, A at A<sup>6</sup>, I at A<sup>7</sup>, C at A<sup>8</sup>, Q at A<sup>10</sup>, I at A<sup>11</sup>, E at A<sup>12</sup>, Y at A<sup>13</sup>, F at A<sup>15</sup>, G at A<sup>16</sup>, D at A<sup>17</sup>, F at A<sup>18</sup> show inhibitory properties. The specification does not provide any other use for the peptides within formula (1) other than as viral inhibitors. One in the art therefor would not know what to use those peptides embraced within formula (1) that do not have inhibitory properties, for example. One in the art would not know how to use 701, for example. Claim 11 comprises specific sequences that do not contain E at A<sup>4</sup>, A at A<sup>6</sup>, I at A<sup>7</sup>, C at A<sup>8</sup>, Q at A<sup>10</sup>, I at A<sup>11</sup>, E at A<sup>12</sup>, Y at A<sup>13</sup>, F at A<sup>15</sup>, G at A<sup>16</sup>, D at A<sup>17</sup>, F at A<sup>18</sup> and based on the instant specification (Table 1) and would therefore not be expected to have those antiviral properties associated with LAP, for example. The

structure of Formula (1) has not been demonstrated to correlate with the asserted activity of viral inhibition. One in the art would be required to perform undue experimentation to practice the instant invention since one would be required to perform undue trial and error experimentation to determine what particular uses those species within formula (1) have that do not possess antiviral properties, for example.

Applicants arguments filed 3/15/04 have been considered but they are not sufficient to overcome the rejection of record. Applicant asserts that the claims have been narrowed and that SEQ ID NO: 3 should not be included in the rejection. Applicant offers no specific arguments as to how the rejection of record is improper. SEQ ID NO: 3 is believed to be correctly included in the rejection of record since the invention is drawn to antivirals and SEQ ID NO: 3 has simply been shown in the specification not to have antiviral capacity.

Any rejection not repeated from the previous Official Action has been withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sean R. McGarry', with a long horizontal flourish extending to the right.

Sean R McGarry  
Primary Examiner  
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